IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

OAK HILL HOMETOWN PHARMACY

Petitioner,

v. CIVIL ACTION NO. 2:19-cv-00716

UTTAM DHILLON, et al.,

Respondents.

MEMORANDUM OPINION AND ORDER

The question before the court is whether a sufficient factual basis existed to justify the United States Drug Enforcement Administration ("DEA") issuance of an *ex parte* emergency order immediately suspending the petitioner's, Oak Hill Hometown Pharmacy ("the Pharmacy"), registration to distribute controlled substances. I find that the DEA did not provide such a factual basis and therefore **DISSOLVE** the Order of Immediate Suspension of Registration ("ISO").

I. Factual Background

The opiate crisis has had a devastating effect on West Virginia. Addiction is a "fundamental neurological disorder," characterized by the American Society of Addiction Medicine, as a "bio-psycho-social-spiritual illness." Pet'r's Ex. 1–7, American Society of Addiction Medicine, *National Practice Guideline*, 4 (June 1, 2015) [ECF No. 12]. Because of the effect of opiate addiction on the body and brain, medical consensus recommends medication assisted treatment ("MAT") over "abrupt cessation of opioids." *See e.g.*, *id.* at 7. Access to effective treatment is of course essential. Yet in West Virginia—as well as many other parts of the country—access is limited. Many clinics in West Virginia have reached patient capacity, forcing prospective patients

seeking treatment onto long waitlists. Additionally, many West Virginian pharmacies refuse to participate in MAT therapy because of the stigma of addiction or their fear of wholesalers declining to engage in business with them. I am personally familiar with the effect of opioids on this community from my decades of work with defendants on supervised release who desperately need treatment.

MAT therapy carries its own set of legal barriers to access. MAT therapy frequently involves the legal prescription of buprenorphine-based medications. There are two types of buprenorphine-based medications. The first type is Subutex, which is a single entity buprenorphine product (also known as a "buprenorphine-mono-product"). The second type is Suboxone, which is a combination product containing buprenorphine and naloxone. In 2002, the FDA approved both Subutex and Suboxone for treatment of Opioid Use Disorder. Buprenorphine is itself an opioid medication, susceptible to abuse and diversion. It is listed as a Schedule III controlled substance. That said, I find it important to keep in mind that Suboxone and Subutex are to be used to treat addiction.

Given the controlled substance status, Subutex and Suboxone require registration for prescription and distribution under the Controlled Substances Act. The registration requires a distributor to monitor for suspicious orders of controlled substances, including orders of "unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b). Congress vested the DEA with the power to "suspend or revoke a license on various grounds, including a finding that the registrant… has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. § 824(a)(4). Typically, before revoking a registration the DEA must issue an Order to Show Cause, describing the grounds for revocation, and conduct a hearing in

accordance with the APA. § 824(c); 21 C.F.R. § 1301.37(c). Following the hearing, the presiding administrative law judge ("ALJ") makes a recommendation to the DEA administrator, who issues a final ruling on that recommendation. *Id.*

The statute also authorizes an *ex parte* emergency suspension procedure, which immediately suspends registration—without a pre-deprivation hearing—simultaneously with the institution of the administrative proceedings. 21 U.S.C. § 824(d)(1). To justify an ISO, the DEA administrator must show that the continued registration of the registrant poses an "imminent danger to the public health or safety." *Id.* In 2016, Congress amended the statute, imposing an even higher threshold for issuing this emergency suspension procedure. *See* Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub. L. No. 114-145, § 2, 130 Stat. 353 (codified as amended at 21 U.S.C. § 824(d)(2)). That amendment defined "imminent danger to the public health or safety" as requiring a showing of "a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration." *Id.* This statutory requirement means that "apart from the onerous task of demonstrating a link between a registrant's alleged transgressions and an impending death, serious bodily harm, or abuse, the Agency now must shoulder the burden of showing that the 'likelihood' of those evils, based on the purported transgressions, is 'substantial.'" John J. Mulrooney, II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 Marq. L. Rev. 333, 346 (2017).

An ISO is not a final agency order but rather an emergency suspension that remains in effect until the conclusion of the administrative proceeding, "unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction." 21 U.S.C. § 824(d). Case law has interpreted the "court[s] of competent jurisdiction" to mean the United States District Courts.

See e.g., Novelty Distributors, Inc. v. Leonhart, 562 F. Supp. 2d 20, 28 (D.D.C. 2008); *Norman Bridge Drug Co. v. Banner*, 529 F.2d 822, 823 (5th Cir. 1976). Oddly enough, the ISO is not reviewable by the administrative law tribunal. *See* Barry M. Schultz, M.D.; Decision and Order, 76 Fed. Reg. 78,695 (Dec. 19, 2011). And the administrative proceeding has no effect on the ISO. *See id.*

On August 6, 2019, the DEA issued an ISO of the petitioner's registration. The Pharmacy is a locally owned pharmacy in Oak Hill, West Virginia, founded in 2012. Pet'r Ex. 1–1, U.S. DOJ DEA, Order to Show Cause and Immediate Suspension of Registration, 2 (Aug. 6, 2019) [ECF No. 12]. The Pharmacy is registered with the DEA to handle controlled substances in Schedule II through V. *Id.* The Pharmacy's registration expires by its own terms on December 31, 2021. *Id.* The DEA originally served an administrative warrant against the Pharmacy on November 28, 2018, initiating an open investigation into the Pharmacy's practices. Since the suspension of its registration on August 6, 2019, the Pharmacy's business has struggled. *See* TRO Hr'g Tr. 48:10–14, Oct. 24, 2019 [ECF No. 16]. The suspension affected the Pharmacy substantially because wholesalers terminated their agreements to fill the Pharmacy's medication orders due to the ISO. Pet'r Ex. 2 [ECF No. 12–2]. On October 21, 2019, the Pharmacy filed a motion for Temporary Restraining Order ("TRO") against the ISO [ECF No. 4]. The matter is ripe for adjudication.

The petitioner requests a dissolution of the ISO. Pet'r Mem. in Supp. of Mot. For TRO, 3 [ECF No. 4]. The enabling statute grants this court the specific power to dissolve the extraordinary action by a government agency of suspending registration without due process. *See* 21 U.S.C. § 824(d). Although the Pharmacy characterizes this request for dissolution as a motion for TRO under Rule 65, that rule is meant to provide temporary relief before a matter can be decided on the merits. *See* Fed. R. Civ. Pro. 65. Because I do not find a sufficient factual basis for the DEA's ISO,

I find that it is more appropriate—given the statutory grant—to deal with this case as a motion to dissolve the ISO rather than as a TRO.

II. Standard of Review

Congress vests this court with the power to dissolve, not review, the ISO. *See* 21 U.S.C. § 824(d). The court owes deference to the DEA's findings of fact. But this court has original jurisdiction to dissolve the DEA's determination to issue an ISO based on those facts. *See Norman Bridge Drug Co. v. Banner*, 529 F.2d 822, 824 (5th Cir. 1976) ("[t]he plain language of this section [21 U.S.C. 824(d)] means that one faced with becoming the victim of the harsh expedient of suspension without prior notice may resort to the appropriate district court in search of appropriate relief.").

Neither the Supreme Court nor Fourth Circuit has addressed what standard of review to apply when reviewing an ISO. The Supreme Court has, however, explained that "de novo review [of an agency decision] is appropriate only where there are inadequate factfinding procedures in an adjudicatory proceeding, or where judicial proceedings are brought to enforce certain administrative actions." *Camp v. Pitts*, 411 U.S. 138, 142 (1973), citing *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971). The emergency context of issuing an ISO does not provide any factfinding procedure or due process to a registrant—except for the vehicle of challenging the decision in a U.S. District Court. Moreover, the administrative proceeding does not provide any "factfinding procedures" regarding the *ex parte* ISO. Due to this lack of administrative process and because of my statutory authority, I find a de novo review of the DEA's conclusions drawn from its findings of fact is appropriate.[1]

[1] It is important to note that other jurisdictions have applied a more deferential standard of review—determining whether the DEA's decision was arbitrary and capricious—in evaluating a TRO or an APA challenge to an ISO. *See e.g., Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d

III. The Administrative Record

Generally, judicial review of an agency decision is limited to the information in the record before the agency at the time it made its decision. *See Camp v. Pitts*, 411 U.S. 138, 142 (1973); *IMS P.C. v. Alverez*, 129 F.3d 618, 624 (D.C. Cir. 1997); *Walter O. Bosswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984) ("[i]f a court is to review an agency's action fairly, it should have before it neither more nor less information than did the agency when it made its decision."). The administrative record is not limited to the four-corners of the ISO, but "consists of all documents and materials directly or indirectly considered by agency decision-makers and includes evidence contrary to the agency's position." *Dewey MacKay v. Cameron Bolman et al.*, No. 2:09-cv-00285 CW at *3 (D. Utah Apr. 7, 2009).

An oddity of the statutory procedure in reviewing an ISO is that there is frequently an incomplete or no certified record to review. *See e.g.*, *Bates Drug Stores, Inc. v. Holder*, No. CV-11-0167-EFS, 2011 WL 1750066, at *3 (E.D. Wash. May 6, 2011) ("the Court cannot consider the administrative record because one does not exist."); *see also Dewey MacKay*, No. 2:09-cv-00285 CW at *2–3 (finding that the administrative record was incomplete). "When faced with an inadequate administrative record, the record may be supplemented to provide, for example, background information or evidence of whether all relevant factors were examined by an agency..." *Holiday CVS, L.L.C. v. Holder*, 839 F. Supp. 2d 145, 155 (D.D.C. 2012).

Here, unlike in *Holiday*, the administrative record is not just inadequate, it is nonexistent.[2] When the administrative record is not defined, courts are forced to surmise what was before the

203, 214 (D.D.C. 2012); *Holiday CVS, L.L.C. v. Holder*, 839 F. Supp. 2d 145, 158 (D.D.C.) (vacated and remanded on other grounds 493 F. App'x 108 (D.C. Cir. 2012); *Novelty Distributors, Inc. v. Leonhart*, 562 F. Supp. 2d 20, 29 (D.D.C. 2008); *Easy Returns Worldwide, Inc. v. United States*, 266 F. Supp. 2d 1014, 1021 (E.D. Mo. 2003).

[2] Mr. McGonigal: "When I make this point, I always get stuck because I circle back around to

administrator at the time of his or her decision. It is therefore appropriate for me to consider all readily available information likely to have been considered by the DEA administrator in deciding that the continued registration of the Pharmacy posed an "imminent danger to public health and safety."

In the hearing on this matter, the Government listed three sources that the administrative record definitely contains: (1) "the immediate suspension order itself;" (2) "the West Virginia Board of Pharmacy and prescription drug monitoring program data;" and (3) the DEA expert's report. TRO Hr'g Tr. 46:7–8, Oct. 23, 2019 [ECF No. 15]. However, the Government admits that the administrative record before the DEA administrator is not necessarily limited to these three sources and may include other material. *See* TRO Hr'g Tr. 5:25; 6:1–5, Oct. 24, 2019 [ECF No. 16]. And in fact, the court knows that the DEA administrator considered other material in reviewing the Pharmacy's registration because the ISO cites additional sources and because witness testimony demonstrates that pharmacy employees were interviewed by the DEA.

That information includes guidance from the United States Department of Health and Human Services—including United States Food and Drug Administration ("FDA") and Substance Abuse and Mental Health Services Administration ("SAMHSA")—and from the American Society of Addiction Medicine ("ASAM") because these sources are referenced in the ISO. It is clear from the ISO that the administrator had the Pharmacy patient records. Pet'r Ex. 1–1, U.S. DOJ DEA, Order to Show Cause and Immediate Suspension of Registration, 10, n.9 (Aug. 6, 2019), [ECF No. 12] ("[p]rior to the AIW [Administrative Investigative Warrant], the U.S. Attorney's Office for the Southern District of West Virginia obtained an Order… that authorized

saying the record that was before the agency, right." The COURT: "Yes" Mr. McGonigal: "And I realize I can't tell you what that was." TRO Hr'g Tr. 5:25; 6:1–5, Oct. 24, 2019 [ECF No. 16].

certain patient records (specifically, those related to substance abuse treatment) to be disclosed to agencies and individuals within the federal government."). Thus, the administrative record should also include any pharmacy patient records of patients who received prescriptions that the DEA flagged as indicative of diversion or abuse.

Witness testimony at the hearing on this matter from Martin Njoku and Lydia Sanford—both employees at the Pharmacy—establishes that DEA agents interviewed them on November 28, 2018 about the Pharmacy's practices including the filling of out-of-state prescriptions for Subutex. *See* TRO Hr'g Tr. 23:12–14 (Sanford), 44:3–14 (Njoku), Oct. 24, 2019 [ECF No. 16]. The Pharmacy's employee statements to the DEA about the Pharmacy practices regarding controlled substances would have been information the DEA administrator had when he made his decision to issue the ISO.

At the hearing, the Pharmacy moved to introduce the binder marked Exhibit 1 [ECF No. 12]. The Government objected—except to the following: Tab 1–Ex Parte Suspension Order; Tab 2–Declaration of Martin Njoku (as limited to the purpose of showing irreparable harm to the Pharmacy); Tab 7–ASAM National Practice Guideline (as it is cited to in the ISO); Tab 20–OHHP PDMP Data; and, Tab 21–Out-of-State Subutex Accepted After AIW. The court **GRANTS** the Government's objection as to: Tab 3–WV Board of Pharmacy Letter; Tab 4–WV Board of Pharmacy Inspector's Report; Tab 5–March 2017 Board of Pharmacy Minutes; Tab 6–WV DHHR MAT White Paper; Tab 13–OHHP BOP Dismissal; and, Tab 14–OHHP BOP Inspection Reports.

IV. The Merits of the ISO

The bar for issuing an *ex parte* emergency suspension of a pharmacy's registration is high. The DEA must show the continued registration of the Pharmacy poses an "imminent danger to public health and safety." 21 U.S.C. § 824(d). The enabling statute defines "imminent danger to

the public health or safety" as requiring that the DEA show "a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration." *Id.* Under DEA regulations, the ISO must contain "a statement of [the administrator's] findings regarding the danger to public health or safety." 21 C.F.R. § 1301.36(e) (2013).

Here, the DEA fails to show an "imminent danger to public health and safety." This standard requires more than mere surmise of abuse and diversion of a controlled substance. Simply demonstrating an unquantified risk of illegal drug use is not a finding of imminent danger. The DEA has not pointed to a single instance of violation of the law. The DEA does not even contend that a specific patient abused or diverted Subutex or Suboxone. The DEA simply offers what it sees as a suspicious pattern of the filling of lawful prescriptions for medication designed to treat opiate addiction.

The ISO identifies what it calls "red flags," suggesting that Subutex, a buprenorphine-mono-product, is in the agency's judgment more subject to abuse and diversion than Suboxone, a combination product containing buprenorphine and naloxone. The DEA thus assumes that prescriptions for Subutex to patients who can tolerate naloxone—i.e. patients who are not pregnant and do not have a naloxone allergy—are always indicative of potential illicit drug use.[3] Yet, the

[3] Both Subutex and Suboxone are susceptible to abuse and diversion. Naloxone is an opioid antagonist and therefore helps to block the euphoric high resulting from injecting buprenorphine products. The inclusion of naloxone in medication thus may deter injection of the product "by persons with active substantial heroine or other full mu-opioid dependence." Determination that Subutex (Buprenorphine Hydrochloride) Sublingual Tablets, Equivalent 2 Milligrams Base and Equivalent 8 Milligrams Base, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness, 80 Fed. Reg. 8080, 8089 (Feb. 13, 2015). However, other persons with opioid dependence especially, "those with a low level of full mu-opioid physical dependence or those whose opioid physical dependence is predominantly to buprenorphine" can abuse buprenorphine/ naloxone combination products through injection or intranasal route. *Id.*

Government has not pointed to a single law or regulation that forbids prescribing Subutex to patients for whom the use of naloxone is safe. The FDA is clear that Subutex is recommended for patients who are pregnant and have naloxone allergies. *See* Determination that Subutex (Buprenorphine Hydrochloride) Sublingual Tablets, Equivalent 2 Milligrams Base and Equivalent 8 Milligrams Base, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness, 80 Fed. Reg. at 8089. However, there is contradictory information from the FDA about whether Subutex should be prescribed to other patients and to the relative risk of abuse and diversion of Subutex as compared to Suboxone.[4] Therefore, the DEA administrator's repeated treatment of Subutex prescriptions as conclusively indicative of abuse and diversion is not supported. It can only be said definitively that Subutex prescriptions for the average patient may be suspicious. I find that the agency has not found facts determining an "imminent danger to public health and safety."

The ISO isolates six additional "red flags:"

1. Multiple prescriptions were written by prescribers outside of West Virginia
2. Approximately 96% of the prescriptions were paid for with cash.
3. The patients, who resided in southern West Virginia, traveled great distances to Western Pennsylvania to obtain the prescriptions.
4. Most of the patients traveled a significant distance to have the prescriptions filled at the Pharmacy, and in doing so, eschewed pharmacies much closer to

[4] Some FDA approved medication labels indicate that Subutex should be prescribed only to pregnant women and people with naloxone allergies. *See* SUBUTEX Medication Guide Indivior Inc. (Feb. 2018) available at https://www.accessdata.fda.gov/drugsatfdadocs/label/2018/020732s018lbl.pdf ("[t]he use of Subutex for unsupervised administration should be limited to those patients who cannot tolerate Suboxone…"). But the FDA has also been clear that Subutex does not have an increased potential for abuse as compared to Suboxone. Pet'r Ex. 1–8, FDA "Dear Pharmacist" Letter (Oct. 2018) [ECF No. 12] ("[a]ll products [Subutex and Suboxone] can be used for maintenance"); Determination that Subutex (Buprenorphine Hydrochloride) Sublingual Tablets, Equivalent 2 Milligrams Base and Equivalent 8 Milligrams Base, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness, 80 Fed. Reg. at 8089 ("[b]ased on our independent review of the available data and published studies on relative abuse liability of Subutex and Suboxone, we do not have sufficient information at this time to determine that Subutex poses an increased potential for abuse or misuse relative to Suboxone.").

their homes.

5. Many of the prescriptions were not filled entirely at the first presentment. Instead, the Pharmacy routinely filled the prescriptions piecemeal over multiple visits.
6. The Pennsylvania prescribers in question appeared to be "pattern prescribing.

Pet'r Ex. 1–1, U.S. DOJ DEA, Order to Show Cause and Immediate Suspension of Registration, 3–8 (Aug. 6, 2019), [ECF No. 12]. These additional "red flags" all stem from and are magnified by the fact that the Pharmacy was filling prescriptions for Subutex. *See* TRO Hr'g Tr. 54:21–25, Oct. 23, 2019 [ECF No. 15] (Mr. McGonigal: "[t]here is no question if they [patients] had been driving all the way to Pennsylvania to get Suboxone that it would have been far less suspicious. You could say that the fact that it was Subutex was the primary triggering red flag."). Thus, if the premise that Subutex prescriptions for patients who can tolerate naloxone demonstrates imminent danger to public health and safety is faulty then the information contained in the ISO is of little value.

The practical reality and context of West Virginia turn these additional flags from red to yellow. The lack of available local MAT providers explains why many West Virginians seek treatment outside the state. *See* TRO Hr'g Tr. 26:11–21(Sanford), 44:8–25 (Njoku), Oct. 24, 2019 [ECF No. 16]. Additionally, most West Virginia providers require a higher number of monthly appointments than Pennsylvania providers, which can be difficult for patients to schedule around work and other commitments. *Id.* Many people do not have health insurance or insurance will not cover Subutex, which forces patients to pay out-of-pocket for medication. *See id.* at 26:11–21 (Sanford). All of this information was before the DEA administrator because the Pharmacy's owner, Martin Njoku, and employee, Lydia Sanford, offered it as explanation to answer the DEA investigators' questions in November 2018. *See id.* at 22:24–25, 23:1–7, 26:11–21, 30:21–23, 31:2–12 (Sanford testifying to what she told DEA investigators); *see also id.* at 44:8–25, 45:20–

25 (Njoku testifying to what he told DEA investigators). It is also well known and often commented upon that medical care providers in West Virginia, including physicians and pharmacies, are reluctant to fill prescriptions for buprenorphine-based treatment medications, meaning that even if patients live near a pharmacy, they may have to travel long distances to access their medication. These additional "red flags" taken together may raise some degree of suspicion regarding the Pharmacy's practices but none of them are facts supporting a finding that the Pharmacy practices presented an "imminent danger to public health and safety."

Furthermore, the fact that after November 28, 2018, when the administrative warrant was served, the Pharmacy substantially curtailed filling prescriptions that the DEA flagged as indicative of abuse and diversion demonstrates that any danger posed by the Pharmacy is not imminent. The DEA continually points to the 2,000 prescriptions for Subutex filled by the Pharmacy between December 2016 to March 2019 as suggesting abuse and diversion. The DEA however must show more than suspicion that these prescriptions indicate abuse and diversion that would rise to the level of a danger to public health and safety. The statute by its own terms requires the DEA factually establish that the continued operation of the Pharmacy poses an imminent danger. This standard means that there must be evidence that the Pharmacy was filling prescriptions that patients were abusing or diverting at the time the agency issued the ISO in August 2019.

The Pharmacy accepted only three new out-of-state prescriptions for Subutex after November 28, 2018. Pet'r's Ex. 1–20, Prescription Drug Monitoring Program Data, [ECF No. 12]. The Pharmacy filled a single prescription for two of those patients, N.R. and M.V., on November 29, 2018, the day after the warrant was served. *Id.* On that date, the Pharmacy told those two patients that the Pharmacy was no longer accepting prescriptions for Subutex. Pet'r's Ex. 1–23,

OHHP Patient Profile N.R. (Nov. 01, 2016–Aug. 08, 2019) [ECF No. 12]; Pet'r's Ex. 1–24, OHHP Patient Profile M.V. (Nov. 01, 2016–Aug. 08, 2019) [ECF No. 12]. The third new patient, J.J.2., was pregnant and thus should not have raised any "red flags." Pet'r's Ex. 1–22, OHHP New Out-of-State Subutex Prescriptions [ECF No. 12]. Aside from these three patients, the Pharmacy permitted nineteen patients with out-of-state Subutex prescriptions to obtain the balance of their prescriptions which had been partially filled prior to the administrative warrant. Pet'r's Ex. 1–20, Prescription Drug Monitoring Program Data [ECF No. 12]. The Pharmacy's "red flag" activity since the administrative warrant thus appears quite limited. The Pharmacy's practices after the administrative warrant was served in November 2018 simply do not support a finding of imminent danger almost nine-months later in August 2019, when the ISO was issued.

Finally, evaluating the "imminent danger to public health and safety" is two-sided. This court must determine whether the continued registration of the Pharmacy poses a "substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur." But this court must also consider the "imminent danger to public health and safety" posed by shutting down access to MAT therapy. And by further limiting the number of pharmacies in West Virginia willing to provide this much needed treatment medication. The underlying reality of MAT therapy is that it requires pharmacies to fill prescriptions of controlled substances for people addicted to opiates—a group of people who frequently face a significant amount of stigma and suspicion. We should be skeptical of allowing such suspicions to erect barriers to legal treatment.

The Controlled Substances Act's purpose is plain: "[t]o deal in a comprehensive fashion with the growing menace of drug abuse in the United States." H.R. Rep. No. 91-1444, at 4567 (1970). The DEA was designed in part to enforce this statute, tackling head-on the criminal

abuse of controlled substances. Although buprenorphine is a controlled substance, I cannot ignore the purpose of Subutex and Suboxone. These medications play an essential role in addressing the "menace of drug abuse in United States."

We cannot solve addiction to opioids solely through criminal law enforcement. This epidemic also requires medical intervention. When the government uses tools that were chiefly developed to crackdown on illegal drugs to impede the lawful prescription of substances for MAT therapy, it may erect barriers to that necessary medical intervention. *See* Molly Doernberg et, al., *Demystifying buprenorphine misuse: Has fear of diversion gotten in the way of addressing the opioid crisis?* 40 Substance Abuse J. 148 (Apr. 22, 2019) available at https://www.tandfonline.com /doi/abs/10.1080/08897077.2019.1572052?journalCode=wsub20. Legal pain management opiates are the primary culprits in the opioid epidemic. The set of controlled substances used medically to treat pain are a far different species of opiate than Suboxone and Subutex—necessary to treat addiction. *See* Michelle Lofwall and Sharon Walsh, *A Review of Buprenorphine Diversion and Misuse: The Current Evidence Base and Experiences from Around the World*, 8(5) J. Addiction Med. 315 (Sept.–Oct. 2014) ("[i]n the United States…the number of deaths involving sublingual buprenorphine products (including generics) that are specifically approved by the Food and Drug Administration for the indication of opioid dependence treatment from 2002 to October of 2013 totaled 464."); Center for Disease Control, *Drug overdose deaths hit record numbers in 2014*, (Dec. 14, 2015) available at https://www.cdc.gov/media/releases/2015/p1218-drug-overdose.html ("[f]rom 2000 to 2014 nearly half a million Americans died from drug overdoses").

The Government repeatedly argues that Subutex is susceptible to abuse and diversion—which is undoubtedly true. The Government states that the Pharmacy allowed patients to partially fill their prescriptions, which is a fact. The Government also points to the records that show that

the Pharmacy filled prescriptions of patients who had out-of-state prescriptions and who travelled far distances to come to the Pharmacy. But the Government does not point to a single instance of abuse and diversion of Subutex, or any other medication, by a patient who filled their lawful prescription at the Pharmacy.

This court **FINDS** that the DEA has not demonstrated that the immediate suspension of the Pharmacy's registration is necessary to prevent an "imminent danger to public health and safety." The court thus **DISSOLVES** the Immediate Suspension Order. This decision is limited to the dissolution of the ISO and is no part of the pending administrative proceeding. The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party. The court further **DIRECTS** the Clerk to post a copy of this published opinion on the court's website, www.wvsd.uscourts.gov.

ENTER: October 30, 2019

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE